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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/596,303	01/26/2007	Hiromi Matsuzaki	P30093	5121

7055 7590 12/01/2008

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EXAMINER	
WOLF, MEGAN YARNALL	
ART UNIT	PAPER NUMBER
3738	

NOTIFICATION DATE	DELIVERY MODE
12/01/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

gbpatent@gbpatent.com
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Office Action Summary	Application No.	Applicant(s)	
	10/596,303	MATSUZAKI ET AL.	
	Examiner	Art Unit	
	MEGAN WOLF	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,10-16 and 19-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-8,10-16 and 19-21* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *071508*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 10/15/08 has been entered.

Response to Arguments

2. Applicant's arguments filed 9/24/08 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-4, 7, 8, 10, 14, 19, and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Boyle et al. 2002/0026242 in view of Kim et al. 5,645,596 (submitted in IDS).

Re claim 1, Boyle discloses the invention substantially as claimed including a bone replacement material to be used by being packed into a bone defective part, wherein the bone replacement material consists essentially of a calcium phosphate

based compound (see hydroxyapatite in par.40) and is formed into a pellet wherein the pellet has a roughly polyhedral shape and is defined by a plurality of surfaces including a pair of opposite, non-parallel surfaces, one of the opposite, non-parallel surfaces being inclined at a predetermined angle with respect to the other of the opposite, non-parallel surfaces (figs.8-12). However, Boyle does not disclose that the bone replacement material has a porosity is equal to or less than 75%.

Kim teaches a vertebral prosthesis, in the same field of endeavor, wherein the porosity of the calcium phosphate is preferably between 30 and 45% for the purpose of simultaneously providing the mechanical strength and tissue ingrowth (col.4, ll.32-46).

It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the porosity of the implant of Boyle to have less than 75% porosity as taught by Kim in order to allow for tissue ingrowth for anchoring the implant while maintaining mechanical strength to resist compression forces.

Re claims 2-4, 7, 8, 10, and 14, see Boyle figs. 8, 10, and 11.

Re claim 19, see Kim col.4, ll.25-30.

Re claim 20, the device of both Boyle and Kim are intended for use in a defect of a vertebral body.

5. Claims 1-6, 10, 14-16, and 19-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carrison et al. 2005/0038517 in view of Kim et al. 5,645,596.

Re claim 1, Carrison discloses the invention substantially as claimed including a bone replacement material to be used by being packed into a bone defective part, wherein the bone replacement material is a rigid biocompatible material (par.45) and is

formed into a pellet wherein the pellet has a roughly polyhedral shape and is defined by a plurality of surfaces including a pair of opposite, non-parallel surfaces, one of the opposite, non-parallel surfaces being inclined at a predetermined angle with respect to the other of the opposite, non-parallel surfaces (fig.3). However, while Carrison discloses that the material may be porous (par.52), Carrison does not disclose that the bone replacement material is calcium phosphate and has a porosity equal to or less than 75%.

Kim teaches a vertebral prosthesis, in the same field of endeavor, wherein calcium phosphate is used for the purpose of its spontaneous adhesion to the associated vertebrae, and wherein the porosity of the calcium phosphate is preferably between 30 and 45% for the purpose of simultaneously providing the mechanical strength and tissue ingrowth (col.4, ll.32-46).

It would have been obvious to one of ordinary skill in the art at the time of the invention to use calcium phosphate with a porosity of less than 75% as taught by Kim for the vertebral implants of Boyle in order to allow for tissue ingrowth for anchoring the implant while maintaining mechanical strength to resist compression forces.

Re claims 2-4, 10 and 14, see Carrison fig.3.

Re claims 5 and 6, while Carrison does not specifically disclose that the implant is either a pentahedral or a triangular prism shape, these shapes are simply a matter of design choice and as it has been held that changes in shape are a matter of design choice, which a person of ordinary skill in the art would have found obvious as they

were not disclosed as being critical to the practice of the invention (In re Dailey, 357 F.2d 669, 149 USPQ 47 (CCPA 1966) MPEP 2144.04 IV B).

Re claims 15, 16, 20, and 21, see Carrison figs. 13-18. Note that while Carrison does not disclose that the implants are inserted into the hollow passage of a cylindrical member such that the inclined surface of a pellet faces the inclined surface of an adjacent pellet, because of their shape shown in fig.3, the pellets of Carrison are capable of such use.

Re claim 19, see Kim col.4, ll.25-30.

6. Claims 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carrison et al. 2005/0038517 in view of Kim et al. 5,645,596 as applied to claim 1 above, and further in view of Shimp 2004/0052829. Carrison in view of Kim discloses the invention substantially as claimed and as discussed above. However, Carrison in view of Kim does not disclose the specific size of the pellets to be between 2 and 10 mm or the volume of each pellet to be in the range of 13 to 239 mm3. Shimp teaches calcium phosphate pellets (par.28), in the same field of endeavor, wherein the pellets can vary in size but are preferably up to 4mm, for the purpose of providing an injectable load bearing support at the repair site (par.10). It would have been obvious to one of ordinary skill in the art at the time of the invention to specify the claimed size ranges for the pellets of Carrison as this size is best suited for injecting bone replacement material into a bone defect in the spine as taught by Shimp. Also see Lambrecht et al. 2004/0024465 par.31 which teaches the volume of injectable pellets in the claimed range.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MEGAN WOLF whose telephone number is (571)270-3071. The examiner can normally be reached on Monday-Friday 7:00-4:30 EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/M. W./
Examiner, Art Unit 3738

/Bruce E Snow/
Primary Examiner, Art Unit 3738